REMARKS

Entry of this amendment is respectfully requested, as it is believed to be fully responsive to the outstanding rejections, would place the application in condition for allowance, and would not require further search.

Reconsideration and allowance are respectfully requested..

Claims 1-5 and 7-10 were pending. In this response, claims 2 and 3 are cancelled without prejudice and claims 1, 4, and 5 are amended for further clarity. Support for the amendments can be found in the specification and claims as originally filed. For example, Kex2 variants are described, e.g., at page 5, line 19- page 6, line 13. No new matter is added. Accordingly, claims 1, 4, 5, and 7-10 are pending and at issue.

Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 1-5 and 7-10 have been rejected under 35 U.S.C. § 112, first paragraph, for lack of written description. The Examiner contends that the specification does not convey that Applicants had possession of the claimed invention at the time of filing. This rejection is respectfully traversed.

In the context of the written description requirement, it is relevant that Applicants view their invention as the intracellular cleavage of Factor VII by a recombinantly co-expressed protein having Kex2 enzymatic activity. As such, the critical element is the enzymatic specificity of the protease in conjunction with the fact that Factor VII is not a natural substrate for Kex2. Applicants are not claiming proteins having Kex2 enzymatic activity, but rather the combination of Kex2 activity with nascent Factor VII precursors.[1] Therefore, the threshold determination should be, would one of ordinary skill in the art have recognized that, at the time of filing, Applicants were in possession of the co-expression of Factor VII and Kex2 enzymatic activity.

In this response the claims have been amended to encompass the co-expression of Factor VII and a Kex2 variant having Kex2 enzymatic activity, i.e., a protein having a sequence derived from that of wild-type Kex2 and closely enough related to the

[1] It is believed that the Examiner misunderstood a similar statement in the previous Amendment. Applicants intend to convey that it is not the proteins themselves that are being claimed, but rather their use and that this distinction affects the application of 112, first paragraph in terms of written description.

wild-type sequence that Kex2 enzymatic activity is retained. It is Applicants' position that the disclosure of several such Kex2 variants as being useful in practicing the present invention indicates unambiguously that, at the time of filing, Applicants viewed their invention as encompassing at least such Kex2 variants. On this basis, it is respectfully submitted that the present claims satisfy the written description requirement and that this rejection should be withdrawn.

On the basis of the above remarks and document, it is believed that the claims are in condition for allowance, and a determination to that effect is earnestly solicited.

Respectfully submitted,

Date: February 21, 2003

Reza Green, Reg. No. 38,475
Novo Nordisk Pharmaceuticals, Inc.
100 College Road West
Princeton, NJ 08540
(609) 987-5800

Marked-up version of claims showing changes

1. (Twice amended) A method for producing Factor VII comprising (a) cultivation of a mammalian cell line comprising a DNA sequence encoding a [yeast-derived endoprotease] Kex2 variant having Kex2 enzymatic activity and a DNA sequence encoding Factor VII (FVII) in a suitable culture medium, under conditions in which both said endoprotease and said FVII are expressed; and (b) isolation of Factor VII from the medium.

4. (Amended) The method of claim 3 wherein the [yeast Kex2 like endoprotease] Kex2 variant is C-terminally truncated Kex2 and has no transmembrane region.

5. (Amended) The method of claim 4, wherein the [yeast Kex2 like endoprotease] Kex2 variant has an ER retention signal added to the C-terminal end.